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In the Supreme Court of the United States

OCTOBER TERM, 1985

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ST. JAMES HOSPITAL

AND

HUMANA OF ILLINOIS, INC. d/b/a SPRINGFIELD COMMUNITY HOSPITAL

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

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QUESTION PRESENTED

Whether the court of appeals erred in invalidating the regulation of the Secretary of Health and Human Services that established a formula for reimbursing hospitals for the portion of malpractice insurance costs attributable to Medicare patients.

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The Acting Solicitor General, on behalf of the Secretary of Health and Human Services, petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Seventh Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-24a) is reported at 760 F.2d 1460. The opinions of the district courts (App., *infra*, 27a-45a, 46a-47a) are reported at 579 F. Supp. 757 and 584 F. Supp. 618.

JURISDICTION

The judgment of the court of appeals (App., *infra*, 25a-26a) was entered on April 18, 1985. On July 9, 1985, Justice Stevens extended the time for filing a petition for a writ of certiorari to and including August 16, 1985. The jurisdiction of this court is invoked under 28 U.S.C. 1254(1).

STATUTE INVOLVED

Title XVIII of the Social Security Act requires the Federal Hospital Insurance Trust Fund to reimburse hospitals for the "reasonable cost" of services provided to Medicare patients. 42 U.S.C. 1395(b)(1); 42 U.S.C. 1395g(a). The Act defines "reasonable cost" as follows (42 U.S.C. 1395x(v)(1)(A)):

> The reasonable cost of any services shall be the cost actually incurred, * * * and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs * * *. In prescribing the regulations referred to in the preceding sentence, the Secretary shall consider, among other things, the principles generally applied by national organizations or established prepayment organizations (which have developed such principles) in computing the amount of payment, to be made by persons other than the recipients of services, to providers of services on account of services furnished to such recipients by such providers. Such regulations may provide for determination of the costs of services on a per diem, per unit, per capita, or other basis, may provide for using different methods in different circumstances, may provide for the use of estimates of costs of particular items or services * * *, and may provide for the use of charges or a percentage of charges where this method reasonably reflects the costs. Such regulations shall (i) take into account both direct and indirect costs of providers of services * * * in order that, under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this subchapter will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs, and (ii) provide for the making of suitable retroactive

corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive.

STATEMENT

This case concerns the validity of a regulation (App., *infra*, 48a-56a), of the Secretary of Health and Human Services governing reimbursement of hospitals for the "reasonable cost" of treating Medicare patients. The specific issue is reimbursement of malpractice insurance premiums. The regulation and its statutory background are described in our petition for a writ of certiorari in *Heckler* v. *Abington Memorial Hospital*, No. 85-52 (filed July 11, 1985).[1]

The present case involves the claims of two hospitals that sought reimbursement of their malpractice premiums under the so-called "patient utilization" formula on the ground that the Secretary's action in replacing that formula with a "paid claims" formula was invalid. The district courts held the rule invalid because it had an inadequate statement of basis and purpose, was arbitrary and capricious, and violated the Medicare Act.

The court of appeals affirmed. It held that the statistical study on which the Secretary's conclusions were based was inadequate; that the Secretary had failed to ascertain the correlation between actual malpractice losses and premium costs; and that the Secretary failed to determine whether the existing system for compensation of overhead adequately compensated for any imbalance in allocation of malpractice costs (App., *infra*, 8a-15a). The court of appeals also ruled that the

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[1] Copies of the petitions for a writ of certiorari in *Abington*, No. 85-52, and *Heckler* v. *Humana of Aurora, Inc.*, No. 85-53 (filed July 11, 1985), which is a related case, are being served on counsel for respondents.

statement of basis and purpose was inadequate (*id.* at 16a-17a). Finally, the court of appeals concluded that the rule violated the Medicare Act, on the grounds (1) that the Secretary had removed malpractice costs from the general pool without first determining whether the existing system of overhead compensation violated the Act, and (2) that by tying compensation to past losses rather than to risk of future loss, the Secretary violated the Act's requirement to compensate hospitals for their reasonable cost of insurance (App., *infra*, 18a-22a).

REASONS FOR GRANTING THE PETITION

This case involves the same Medicare regulation that is involved in *Abington*, and that is the subject of the pending rulemaking proceeding described in our petition for a writ of certiorari in that case.[2] As in *Abington*, the decision of the court of appeals in this case addresses several issues that may be resolved, or at least brought into sharper focus, by the pending rulemaking proceeding. Therefore, as in *Abington*, we believe that it would be appropriate for the judgment of the court of appeals to be vacated and the case remanded for reconsideration in light of the current rulemaking proceeding.

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[2] In our petition (at 7-8) in *Abington* we cited the various court of appeals decisions that address the validity of the rule. After that petition was filed, the Eighth Circuit held the rule invalid, relying on the decision of the Seventh Circuit in the present case. *Menorah Medical Center* v. *Heckler*, No. 84-2257 (8th Cir. July 24, 1985). In addition, on August 5, 1985, the Ninth Circuit vacated the submission of two related cases pending this Court's disposition in *Abington* and *Humana of Aurora. St. Joseph's Hospital* v. *Heckler*, No. 84-2168; *Albany General Hospital* v. *Heckler*, No. 84-3865.

CONCLUSION

The case should be disposed of in light of this Court's disposition in *Heckler* v. *Abington Memorial Hospital*, No. 85-52.

Respectfully submitted.

LAWRENCE G. WALLACE
*Acting Solicitor General**

AUGUST 1985

* Acting Solicitor General Fried is disqualified in this case.

APPENDIX A

In the

United States Court of Appeals

For the Seventh Circuit

No. 84-1478

ST. JAMES HOSPITAL,

Plaintiff-Appellee,

v.

MARGARET M. HECKLER, Secretary of the Department of Health and Human Services,

Defendant-Appellant.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.
No. 83 C 2773—**Hubert L. Will**, *Judge.*

No. 84-1727

HUMANA OF ILLINOIS, INC., d/b/a Springfield Community Hospital,

Plaintiff-Appellee,

v.

MARGARET M. HECKLER, Secretary of the Department of Health and Human Services,

Defendant-Appellant.

Appeal from the United States District Court for the Central District of Illinois, Springfield Division.
No. 83 C 3061—**J. Waldo Ackerman**, *Judge.*

ARGUED DECEMBER 5, 1984—DECIDED APRIL 18, 1985

Before BAUER and FLAUM, *Circuit Judges*, and GRANT, *Senior District Judge.**

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* The Honorable Robert A. Grant, Senior District Judge for the Northern District of Indiana, is sitting by designation.

FLAUM, *Circuit Judge*. In these consolidated appeals, the Secretary of the Department of Health and Human Services (the "Secretary") seeks reversal of two district court decisions invalidating a regulation promulgated in 1979 under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.* (1982) (the "Medicare Act"). The regulation at issue prescribes a new formula for reimbursing Medicare health care providers for malpractice insurance premiums associated with the care of Medicare patients. 42 C.F.R. § 405.452(a)(1)(ii)(1984) (the "Malpractice Rule"). The district courts below concluded that the Malpractice Rule was invalid because it was arbitrary and capricious and contrary to the Medicare Act and because the Secretary failed to provide an adequate basis and purpose statement. *St. James Hospital v. Heckler*, 579 F. Supp. 757 (N.D. Ill. 1984) (Will, J.); *Humana of Illinois, Inc. v. Heckler*, 584 F. Supp. 618 (C.D. Ill. 1984) (adopting Judge Will's decision).[1] We affirm.

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[1] The Third and Tenth Circuits and fifteen other district courts to date have similarly rejected the Secretary's Malpractice Rule. *See Humana of Aurora, Inc. v. Heckler*, 753 F.2d 1579 (10th Cir. 1985), *rev'g* No. 83-Z-70 (D. Colo. Sept. 19, 1983); *Abington Memorial Hosp. v. Heckler*, 750 F.2d 242 (3d Cir. 1984), *aff'g* 576 F. Supp. 1081 (E.D. Pa. 1983); *Arkansas Methodist Hosp. v. Heckler*, 597 F. Supp. 238 (E.D. Ark. 1984); *East Jefferson Gen. Hosp. v. Heckler*, No. 83-4107 (E.D. La. Oct. 19, 1984); *St. Anthony Regional Hosp. v. Heckler*, No. C 84-37 (N.D. Iowa Oct. 12, 1984); *Parkway Medical Center v. Heckler*, Nos. 83-1700 and 83-1005 (S.D. Fla. Sept. 24, 1984); *Mercy Medical Center v. Heckler*, No. 3-82 CIV 1724 (D. Minn. Aug. 17, 1984); *Menorah Medical Center v. Heckler*, No. 83-0822-CV-W-4 (W.D. Mo. July 26, 1984); *Metropolitan Hosp., Inc. v. Heckler*, No. C-83-502 A (N.D. Ga. June 25, 1984); *DeSoto Gen. Hosp. v. Heckler*, No. 83-1050-B (M.D. La. June 20, 1984); *Alexandria Hosp. v. Heckler*, 586 F. Supp. 581 (E.D. Va. 1984); *Lloyd Noland Hosp. & Clinic v. Heckler*, No. CV83-PT-0868-S (N.D. Ala. Apr. 6, 1984); *Bedford County Memorial Hosp. v. Heckler*, 583 F. Supp. 367 (W.D. Va. 1984); *St. Joseph's Hosp. v. Heckler*, 583 F. Supp. 1545 (D. Ariz. 1984); *Albany Gen. Hosp. v. Heckler*, 584 F. Supp. 614 (D. Or.

(Footnote continued on following page)

I.

A. The Malpractice Rule

Under the Medicare Act, a health care provider is entitled to government reimbursement for the lesser of the "reasonable cost" of the services it provides for Medicare patients or its "customary charges" with respect to those services. 42 U.S.C. § 1395f(b)(1) (1982). "Reasonable cost" is defined as "the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations" to be promulgated by the Secretary. 42 U.S.C. § 1395x(v)(1)(A) (1982). The statute further provides that such regulations shall take into account "both direct and indirect costs of providers of services . . . in order that . . . the necessary costs of efficiently delivering covered services to individuals covered by [Medicare] will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by [Medicare]. . . ." *Id.*

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[1] *continued*

1984); *Chelsea Community Hosp. v. Heckler*, No. 83CV-6126-AA (E.D. Mich. Dec. 20, 1983); *Mt. Carmel Mercy Hosp. v. Heckler*, 581 F. Supp. 1311 (E.D. Mich. 1983).

Although four district courts have upheld the Rule, one case has been reversed on appeal and another has been remanded for further development of the rulemaking record. *See Boswell v. Heckler*, 573 F. Supp. 884 (D.D.C. 1983), *remanded on procedural grounds*, 749 F.2d 788 (D.C. Cir. 1984); *Humana of Aurora, Inc. v. Heckler*, No. 83-Z-70 (D. Colo. Sept. 19, 1983), *rev'd*, 753 F.2d 1579 (10th Cir. 1985); *Cumberland Medical Center v. Heckler*, 578 F. Supp. 39 (M.D. Tenn. 1983), *appeal docketed*, No. 83-5579 (6th Cir. Aug. 9, 1983); *Athens Community Hosp. v. Heckler*, 565 F. Supp. 695 (E.D. Tenn. 1983), *appeal docketed*, No. 83-5546 (6th Cir. Aug. 5, 1983). *See also Benton County Gen. Hosp. v. Heckler*, No. 82-1289 (W.D. Tenn. Oct. 25, 1983) (dismissing challenge to Malpractice Rule on res judicata grounds).

With these directives in mind, the Secretary adopted regulations in 1966 that pooled all of a health care provider's general and administrative ("G&A") costs together and then allocated them among Medicare and non-Medicare patients on the basis of patient hospital usage ("patient utilization ratio"). 31 Fed. Reg. 14,808 (1966) (codified at 20 C.F.R. Part 405, Subpart D (1966)). For example, if Medicare patients constituted 30% of the patient charges at a hospital in a given year, then Medicare reimbursed the hospital for approximately 30% of its G&A costs. G&A costs included a variety of overhead expenses, including billing costs, accounting and legal fees, and all types of insurance premiums. This method of allocating indirect costs remained unchanged from 1966 until promulgation of the Malpractice Rule in 1979.

On March 15, 1979, the Secretary issued the proposed Malpractice Rule for public comment. 44 Fed. Reg. 15,744 (Mar. 15, 1979). The proposed rule removed malpractice insurance premiums from the G&A pool of indirect costs and apportioned them directly based on malpractice loss experience. The stated reason for segregating malpractice insurance premiums from the other G&A costs was that the Medicare program was paying a disproportionate amount of malpractice insurance costs under the old formula. This conclusion was based on "[a] study conducted by an HEW consultant indicat[ing] that malpractice awards for Medicare . . . patients are significantly lower in amount than losses for other patient population [sic]." *Id.* at 15,745.[2] The Secretary attributed the lower awards for Medicare patients to the fact that their income potential and life expectancies are generally less than those of the remainder of the patient population. *Id.*

The proposed rule removed malpractice insurance premiums from the G&A pool and instead reimbursed those costs by dividing the losses paid to Medicare patients

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[2] The study referred to is the *1976 Medical Malpractice Closed Claim Study* dated March 1978 and conducted by Westat, Inc. (the "Westat study"). *See* 44 Fed. Reg. 31,641 (June 1, 1979).

by the total paid malpractice losses, and then multiplying that ratio times malpractice insurance costs. *Id.* The ratio was to be calculated for both the cost year at issue and the four preceding years. The Secretary selected a single provider's five-year malpractice loss ratio as the relevant measure on the theory that "the estimated malpractice losses paid in future periods are closely related to past malpractice losses paid." *Id.* Hospitals with no malpractice loss experience for the relevant five-year period were required to obtain an actuarial estimate of Medicare's share of current malpractice costs from an independent actuary, insurance company, or broker. *Id.*

The Secretary received nearly 600 comments on the proposed rule.[3] The comments were submitted by health care institutions, consumers, accounting firms, insurance companies, actuaries, health care consultants, physicians and nurses, and Medicare beneficiaries. All comments received were opposed to the proposed rule and recommended its complete withdrawal. 44 Fed. Reg. 31,641 (June 1, 1979). There were seven major criticisms of the proposed rule: (1) the inequity of removing malpractice premiums from the G&A pool while retaining in the pool other costs incurred principally for Medicare patients, (2) providers' anticipated cash flow problems due to erratic reimbursement patterns as the paid-loss ratio fluctuates from year to year, (3) the increased likelihood that hospitals would fraudulently treat malpractice claims by Medicare patients, (4) the statistical invalidity of the Westat study, (5) the fact that malpractice insurance protects hospitals' assets and thus benefits all patients equally, (6) the fact that insurance companies set pre-

[3] The Secretary initially provided only a 45-day comment period rather than the normal 60-day period because the proposal was "not complex" and because the Secretary wanted to make the regulation effective for cost reporting periods beginning on or after July 1, 1979. 44 Fed. Reg. 15,745 (March 15, 1979). In response to requests from provider organizations, the Secretary later extended the comment period through May 15, 1979. 44 Fed. Reg. 25,476 (May 1, 1979).

miums on the basis of an overall assessment of risk, without allocating the risk among different types of patients, and (7) the complexity and expense of the additional accounting required by the proposed rule.

Notwithstanding the many adverse comments, the Secretary issued the final Malpractice Rule on June 1, 1979 44 Fed. Reg. 31,641 (originally codified at 42 C.F.R. § 405.452(b)(1)(ii)). The only change to the proposed rule was the formula to be used for providers with no malpractice loss experience. Instead of the actuarial estimate required in the proposed rule, the final rule calculated reimbursement for these providers on the basis of the national ratio of malpractice awards paid to Medicare patients to the malpractice awards paid to all patients. *Id.* at 31,642. This national ratio, set at 5.1% for the first year based on the Westat study, was to be recalculated each year in light of the previous year's data.[4]

B. The Hospitals

Plaintiff-appellees St. James Hospital and Humana of Illinois, Inc. ("Humana") are both health care providers as defined in the Medicare Act. *See* 42 U.S.C. § 1395x(u) (1982). For its cost year ending in 1980, St. James Hospital's overall Medicare patient utilization ratio was 30%. Under the new Malpractice Rule, however, Medicare only reimbursed 20.11% of its malpractice insurance premiums. The amount of denied Medicare reimbursement at issue is $24,159.

On June 3, 1981, St. James sought a hearing on its malpractice reimbursement determination before the

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[4] The Social Security Amendments of 1983 instituted a prospective payment reimbursement system for cost years beginning on or after October 1, 1983. Pub. L. No. 98-21, Title VI, 97 Stat. 149 (1983) (to be codified at 42 U.S.C. § 1395ww). This new system has no effect on the resolution of the issues in this case.

Provider Reimbursement Review Board ("PRRB" or the "Board") pursuant to 42 U.S.C. § 1395oo(a)(1982). The Board held that it had no jurisdiction to review the validity of the Malpractice Rule and therefore, pursuant to statute, certified the question for appeal to the federal district courts. 42 U.S.C. § 1395oo(f)(1)(1982). On appeal, Judge Will held that the Secretary failed to provide an adequate basis and purpose statement for the Malpractice Rule and that the Rule was arbitrary and capricious and not in compliance with the requirements of the Medicare Act. *St. James Hospital v. Heckler*, 579 F. Supp. at 767. St. James Hospital's motion for summary judgment was accordingly granted. *Id.*

The Malpractice Rule's impact on Humana was even greater than its effect on St. James Hospital. Humana's Medicare patient utilization ratio was 49.38% for cost year 1980, yet its reimbursement under the Malpractice Rule was zero. Humana received no Medicare reimbursement because it had only paid a single $750 malpractice award in the relevant five-year period and the recipient of that award was a non-Medicare patient. The amount of denied Medicare reimbursement at issue for Humana is approximately $37,000. On appeal to the district court, Judge Ackerman adopted Judge Will's opinion holding the Malpractice Rule invalid and granted Humana's motion for summary judgment. *Humana of Illinois, Inc. v. Heckler*, 584 F. Supp. 618, 619 (C.D. Ill. 1984).

II.

In assessing the validity of the Malpractice Rule on appeal, we will address three separate, although somewhat interrelated, questions. The first question is whether the Secretary's action was substantively "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," under the judicial review provisions of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551-559, 701 *et seq.* (1982). 5 U.S.C. § 706(2)(A) (1982). The second inquiry is whether the Rule complies with the

procedural requirements of the APA, in particular the statement of basis and purpose required by 5 U.S.C. § 553(c). 5 U.S.C. § 706(2)(D) (1982). The last issue is whether the Rule violates the Medicare Act. Cases invalidating the Malpractice Rule, *see supra* note 1, have based their decisions variously on some or all of the above rationales. We begin by discussing whether the Secretary violated the APA in promulgating the Rule, first substantively and then procedurally, and then move on to address whether the Rule violates the Medicare Act.

A. Arbitrary and Capricious

The scope of review under the "arbitrary and capricious" standard is narrow, for we are not permitted to substitute our own judgment for that of the agency. *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 103 S. Ct. 2856, 2866 (1983). The agency is required, however, to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Id.* at 2866-67. An agency rule may be arbitrary and capricious

> if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Id. at 2867. *See also Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971) (presumption of regularity afforded agency's decision does not shield it from a "thorough, probing, in-depth review"); *City of West Chicago v. United States Nuclear Regulatory Commission*, 701 F.2d 632, 648 (7th Cir. 1983). There is no contention here that the Secretary relied on factors other than those Congress intended her to consider. The purpose of this

review, therefore, is to determine whether the Secretary entirely failed to consider important aspects of the malpractice problem or offered an explanation for the Malpractice Rule that runs counter to the evidence before the agency.

The hospitals' attack on the Malpractice Rule as arbitrary and capricious focuses primarily on the Westat study, since the Secretary issued the Rule based almost exclusively on the findings in the study. The hospitals argue that the Westat study, and hence the rulemaking record, is so deficient that the Secretary's implementation of the Rule was arbitrary and capricious.

The Westat study was sponsored by the Department of Health, Education, and Welfare (predecessor agency to the Department of Health and Human Services) to analyze the frequency and type of malpractice claims and awards between July 1, 1976, and October 31, 1976. The study had a very broad scope, its general purpose being to determine the factors influencing the frequency of occurrence of malpractice claims and the size of awards, so that the level and rate of increase of medical malpractice insurance premiums might be reduced in order to achieve the general policy objective of controlling the cost of health care for *all* patients, not just Medicare patients. Only one of the study's eight chapters addressed Medicare issues.

Westat's analysis of Medicare claims as compared to non-Medicare claims led it to conclude that although Medicare paid for 21% of the hospital discharges in 1973, "only a maximum of 13 percent of the malpractice claims closed in 1976 (for incidents, most of which occurred in 1973) were filed by persons for whom Medicaid [sic] paid for their medical care." In addition to finding that Medicare patients filed fewer claims, the study concluded that "the average award for Medicare patients is considerably smaller than for other groups." With regard to Medicare reimbursement of malpractice insurance costs, however, Westat only surmised that "[i]f the percentage of Medi-

care patients involved in medical malpractice claims is proportionately smaller than the percentage of hospitalizations for which Medicare paid, then Medicare *may* be subsidizing malpractice insurance costs that should actually be covered by other payors" (emphasis in original).

The hospitals first point out the limited scope of the Westat study and argue that the data base was insufficient to justify reliance on the study's conclusions. As noted above, the study surveyed medical malpractice claims closed during a single four-month period in 1976. Data was acquired from only nine of more than fifty private insurance carriers for the four-month period. It appears, however, that insureds from those nine companies were involved in 84% of all malpractice claims closed by private carriers in 1976. Although claims paid by private insurance carriers thus seem to be adequately represented, the use of data from these private carriers alone means that self-insuring providers (usually hospitals) were excluded from the study, as were federal institutions. A study conducted by the American Hospital Association (cited in the Westat study) revealed that in 1976, approximately 20% of non-federal community hospitals in the United States were either partially or totally self-insured. Claims from the totally self-insured hospitals were not reflected in the Westat study, and those from the partially self-insured hospitals were underrepresented.

The authors of the Westat study identified a second source of bias in addition to the study's exclusion of self-insured providers—the fact that Westat did not have complete data on the identity of all defendants in multiple defendant cases. Although the Secretary now speculates that because these omissions relate to defendant identity they are not relevant to the Medicare chapter, where the key factor was plaintiff identity, the study's authors made no such distinctions. In fact, as will be discussed shortly, the Secretary should have paid particular attention to the study's warnings on this source of bias because defendant

identity was indeed an important factor in this rule-making.

Because of the above-noted limitations on the scope of the Westat study, the study's data base consisted of a total of 3,932 medical malpractice claims. Information on the source of payment for medical care was available for only 2,637 (approximately two-thirds) of the claimants. Of those, only 340 claimants, or approximately 12%, were identified as Medicare recipients. With respect to the findings on the size of awards made to Medicare claimants, the pool of information was even smaller. Because less than half of all malpractice claims resulted in awards (for Medicare and non-Medicare claimants alike), award information for Medicare claimants was based on only 166 claims.

The authors of the Westat study cautioned at the outset that readers should keep in mind the limited nature of the study and certain possible sources of bias. With regard to one particular chapter—injury prevention— the authors warned that "[c]onclusions must be drawn very cautiously because of the possibility of biased data." At least one court has noted that the same cautions would seem to apply to all conclusions drawn from the study. *See Boswell v. Heckler*, 749 F.2d 788, 796 & n.11 (D.C. Cir. 1984).

In addition to the cautions contained in the study itself, Westat sent a memorandum to the agency on August 17, 1978, noting deficiencies in the Westat study and making recommendations for future research. The memorandum recommended a more precise sample design if "national estimates or 'representative data'" were desired, pointing out that with the sample design used in the 1976 Westat study, "it was virtually impossible to generalize beyond the sample—to annual totals or to national totals, to cite the most elementary limitations." The authors further stated that "there was no assurance [in the 1976 study] that the sample was in any way

representative, of hospitals[,] of physicians, of injuries, of geographic regions, of claimants." Notwithstanding this memorandum, the Secretary issued the proposed Malpractice Rule seven months later, to have nationwide effect, based almost exclusively on the findings in the Westat study.

The most significant source of bias in the Westat study with respect to the Malpractice Rule, however, is one not noted in the study itself—the fact that the data base included claims against both hospitals and practitioners.[5] Westat based its Medicare analysis on the number of claims filed for injuries *occurring in* hospitals rather than claims filed *against* hospitals. The study found that although hospitals were reported as the site of injury in 78% of all claims in the study, however, hospitals were named defendants in only 32%. Thus, Westat's use of claims for all injuries occurring in hospitals included a fair number of claims filed against physicians for injuries occurring in hospitals.

Claims against hospitals represented only 32% of the claims in Westat's data base, and only 20% of claim dollars in the study. Since the Malpractice Rule is based on *hospital* claims experience only, the study's inclusion of data on claims against physicians permits reliable conclusions with respect to Medicare claimants only if they file claims against hospitals as opposed to physicians in the same proportion as do non-Medicare claimants. This,

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[5] The Secretary contends that this argument cannot be considered at this juncture because it was not made in any public comments on the proposed rule and thus is not part of the rulemaking record. We believe, however, that it was the Secretary's obligation to ensure that the inclusion of claims against physicians did not bias the results of the Westat study before utilizing those results to formulate a rule based solely on claims against hospitals. In other words, it is an agency's duty to establish the statistical validity of the evidence before it prior to reaching conclusions based on that evidence, not the public's duty to inform the agency of statistical invalidities in its evidence.

however, does not appear to be the case. The Westat study itself indicates that 69% of the injuries complained of in paid claims filed by Medicare patients were "institutional problems" (including fluid/specimen administration, falls, medical management, and equipment problems), as compared to 35% for all paid claims. This data suggests that Medicare recipients file a much greater proportion of claims against hospitals than do other patient populations, which tend to file more claims against physicians.

Reanalyzing Westat's data to take account of this potential source of bias produces a startling effect. Westat's analysis concluded that although Medicare paid for 21% of hospital discharges in 1973, only a maximum of 13% of malpractice claims closed in 1976 were filed by Medicare patients, representing 5.1% of dollars paid. When claims against hospitals only are isolated, however, Medicare patients accounted for 20.2% of claims paid and 17.8% of dollars paid.[6] When Westat's data is further refined to exclude claims against hospital-employed physicians (since these claims are excluded from the Malpractice Rule's paid-claim ratio), Medicare patients accounted for 22.5% of claims paid and 19.9% of dollars paid. This result seriously undermines the study's conclusion, heavily relied on by the Secretary in formulating the Malpractice Rule, that the percentage of Medicare patients involved in malpractice claims is substantially smaller than the percentage of hospitalizations (and hence the percentage of indirect G&A costs such as malpractice insurance premiums) paid for by Medicare.

In summary, we agree with the district courts below that the Westat study furnished an inadequate basis for the Malpractice Rule and that the Secretary committed a clear error of judgment in relying on the study as the sole

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[6] This analysis was performed after the Malpractice Rule was promulgated, using Westat's actual data tape, and is therefore not part of the rulemaking record. We cite these results only to demonstrate the possible extent of bias in the Westat study due to the inclusion of claims against physicians.

empirical basis for the Rule. *See St. James Hospital v. Heckler*, 579 F. Supp. at 766. *See also Humana of Aurora, Inc. v. Heckler*, 753 F.2d 1579, 1583 (10th Cir. 1985) ("When an agency adopts a regulation based on a study not designed for the purpose and which is limited and criticized by its authors on points essential to the use sought to be made of it, the administrative action is arbitrary and capricious and a clear error in judgment.").

Compounding the statistical limitations of the study itself, moreover, the Secretary promulgated the Rule without investigating several other important aspects of the malpractice problem, primarily the extent to which any disproportionality in the amount paid on malpractice claims filed by Medicare recipients affected the malpractice insurance costs of providers. The public comments received by the Secretary uniformly criticized the Malpractice Rule's use of actual loss experience as the sole measure of reimbursement for malpractice insurance premiums. Several insurance companies commented that the proposed rule was "illogical" because "past malpractice award experience for a particular patient group does not fairly reflect current malpractice costs attributable to the group." The insurance carriers noted that the cost of insurance depends on factors such as the size of the provider, the number of patients it services, the types of services it provides, and other factors in addition to past claim experience. Other commenters pointed out that administrative expenses such as risk management services, acquisition costs of policy issuance, accounting services, agents' commissions, licensing fees and taxes, unallocated claims expense, and the general administrative overhead expenses of the insurer account for anywhere from 30% to over 50% of premium costs.

The Secretary now belatedly attempts to justify the Malpractice Rule's use of loss experience to reimburse malpractice premium costs by citing to some commenters' statements that despite the various other factors considered when setting premium rates, loss payment is the

largest single element of the malpractice premium. The agency itself, however, made no attempt to examine the relationship between actual loss experience and premium costs before promulgating the Malpractice Rule, apparently assuming that the relationship was strong enough to support the Rule's use of loss experience as the sole measure of premium costs.[7] The Secretary now contends that a few public comments, in the course of criticizing the Malpractice Rule's reliance on this very relationship, confirm that assumption and that the relationship was therefore adequately established in the rulemaking record. This is clearly an insufficient basis upon which to rest a regulation with such substantial economic effects on health care providers. We therefore find that even if the Westat study was statistically valid and its findings reliable, promulgation of the Malpractice Rule was arbitrary and capricious because the Secretary completely failed to ascertain the extent of the correlation, if any, between actual malpractice losses and premium costs.

The Secretary failed to investigate another aspect of the malpractice problem as well. In deciding to remove malpractice insurance costs from the G&A pool, the Secretary neglected to first determine whether the existing pool adequately compensated for any imbalance in the allocation of malpractice costs. This oversight will be more fully discussed in section C, *infra*.

In sum, we find that the Secretary entirely failed to consider several important aspects of the malpractice problem before promulgating the Malpractice Rule, and that the explanation given for the Rule is not adequately supported by the Westat study, the only statistical evidence before the agency. We therefore find the Rule arbitrary and capricious.

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[7] The Westat study's conclusions related solely to actual loss experience, and made no attempt to explore the relationship between loss experience and premium costs.

B. Inadequate Basis and Purpose Statement

The Malpractice Rule is also challenged as violating the procedural requirements of the APA, particularly the requirement that "[a]fter consideration of the relevant matter presented [through notice and comment], the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose." 5 U.S.C. § 553(c) (1982).[8] Although the agency need not respond to every fact or contention in the comments submitted, the basis and purpose statement must identify "what major issues of policy were ventilated by the informal proceedings and why the agency reacted to them as it did." *Automotive Parts & Accessories Ass'n v. Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1968).

We find that the Secretary's basis and purpose statement did not adequately respond to the criticisms raised in the many adverse comments submitted on the Malpractice Rule in several respects. First and foremost, the Secretary made no attempt to respond to comments that the Westat study was statistically unreliable and that its own authors had cautioned against its use in the manner contemplated by the Secretary. The Secretary's *post hoc* attempts to respond to those comments on appeal are insufficient and will not remedy the failure to do so in the basis and purpose statement. *See Motor Vehicles Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 103 S.Ct. 2856, 2870 (1983).

Commenters also criticized the Malpractice Rule on the ground that the accepted insurance industry practice is to calculate premiums on the basis of occupied beds, regardless of the Medicare status of the patient. Thus, the commenters noted, the Malpractice Rule's formula for reimbursing premium costs bears no relation to the actual

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[8] The plaintiff hospitals have not appealed the district courts' determination that the Secretary gave sufficient notice of the proposed rulemaking under the APA. *See St. James Hosp. v. Heckler*, 579 F. Supp. at 763-64. We therefore do not address this issue on appeal.

premium costs incurred by the hospitals on behalf of Medicare recipients. In response to these criticisms, the Secretary stated: "We are aware that insurance companies generally do not determine insurance rates for malpractice insurance based upon the financial status of the patients. However, information about malpractice loss experience by type of patient (i.e., Medicare) is readily available." 44 Fed. Reg. 31,642 (June 1, 1979). Besides being nonresponsive, this statement ignores the fact that in the Secretary's own Westat study, the insurance companies had no information on the Medicare status of the claimant for a full one-third of the claims filed.

The opportunity under the APA to comment on proposed rules is "meaningless unless the agency responds to significant points raised by the public." *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35-36 (D.C. Cir.), *cert. denied*, 434 U.S. 829 (1977). We agree with the district courts' conclusion that the Secretary's basis and purpose statement failed to respond to many significant points made by the public in opposition to the Malpractice Rule. The Secretary's statement of basis and purpose provided no indication of why criticisms of the Westat study were deemed to be invalid, and failed to give a reasoned response to other criticisms of the Rule. We therefore conclude that the Secretary failed to comply with section 553(c) of the APA.

C. Violation of the Medicare Act

The last question for review is whether the Malpractice Rule is contrary to provisions of the Medicare Act. Although the Secretary is ordinarily given a great deal of deference in interpreting and implementing the laws that she is directed to administer, *see Heckler v. Campbell*, 103 S. Ct. 1952, 1957 (1983) (involving Secretary's interpretation of Social Security benefit provisions); *Batterton v. Francis*, 432 U.S. 416, 425 (1977) (same), a lesser degree of deference is required when reviewing the Secretary's actions under the Medicare Act's reimbursement provisions. *See Northwest Hospital, Inc. v. Hospital Service Corp.*, 687 F.2d 985, 990-91 (7th Cir. 1982) (Medicare

statute specifically circumscribes Secretary's discretion to define 'reasonable costs'); *St. John's Hickey Memorial Hospital, Inc. v. Califano*, 599 F.2d 803, 813 (7th Cir. 1979) (Secretary's authority under Medicare Act significantly more circumscribed than authority delegated in Social Security benefit cases); *Mt. Carmel Mercy Hospital v. Heckler*, 581 F. Supp. 1311, 1313-15 (E.D. Mich. 1983) (Secretary's discretion limited in this area). The regulations promulgated under the Medicare Act "*must* ... take into account both direct and indirect costs and *must* avoid the result of shifting costs to non-Medicare patients." *St. John's Hickey Memorial Hospital*, 599 F.2d at 813 n.17 (emphasis added).

The first provision of the Act at issue is the prohibition against shifting Medicare costs to non-Medicare patients and vice versa. 42 U.S.C. § 1395x(v)(1)(A) (1982); *see also Northwest Hospital, Inc. v. Hospital Service Corp.*, 687 F.2d 985, 989 (7th Cir. 1982). As mentioned previously, the Secretary's mechanism for reimbursing providers' indirect costs has consistently been to pool them together as G&A costs and then to reimburse a percentage of those costs on the basis of the provider's Medicare patient utilization ratio. This regulatory scheme was not premised on a belief that all G&A costs applied to all of a hospital's patients equally, but rather on the assumption that some costs would be disproportionately allocated in favor of Medicare patients while others would be disproportionately allocated in favor of non-Medicare patients. Pooling all of the various costs together was believed to be the fairest and most administratively feasible way of allocating indirect costs among Medicare and non-Medicare patients. In addition, although there may have been cost-shifting with respect to a certain item (*i.e.*, billing expenses associated predominately with the Medicare program), the G&A pool as a whole was thought to fairly allocate indirect costs among Medicare and non-Medicare populations such that neither sector impermissibly paid the costs of the other. The Secretary pulled malpractice insurance premiums out of the G&A pool

based on two findings: first, the cost of malpractice insurance skyrocketed in the 1970's, and second, the Westat study led the Secretary to believe that Medicare was paying more than its fair share of that cost. *See* 44 Fed. Reg. 31,642 (June 1, 1979). The problem with this analysis is the findings that were *not* made.

Even assuming that Medicare paid a disproportionate amount of malpractice insurance costs when they were included in the G&A pool, the Secretary seems to have forgotten that the G&A pool was designed to accommodate such imbalances. What is missing in the Secretary's promulgation of the Malpractice Rule is the necessary starting premise: that the G&A pool including malpractice insurance costs, taken as a whole, impermissibly shifted costs attributable to non-Medicare patients to the Medicare program. *See Boswell v. Heckler*, 749 F.2d at 795. If the starting point was otherwise, the removal of a specific cost that *was* disproportionately attributable to non-Medicare patients would inevitably *result* in an imbalanced pool, in violation of the Act. *Id.* The Secretary did not explicitly make this essential preliminary finding.

One could argue that in instigating this rulemaking at all, the Secretary must have made an implicit finding that the then-existing method of allocating indirect costs was inequitable. The problem with this argument, however, is that the Secretary had no factual support for that finding. Although the Secretary had support for the finding that malpractice insurance premiums increased dramatically during the 1970's, for example, no attempt was made to determine whether and to what extent *other* indirect costs in the G&A pool, such as legal fees, also increased over the same time period. *See Boswell v. Heckler*, 749 F.2d at 795 n.8. The Secretary therefore had no information indicating the amount of change in the *percentage* of the G&A pool representing malpractice insurance costs. Without that information, it was impossible to determine whether the G&A pool as a whole impermissibly shifted costs from the non-Medicare to the

Medicare populations. Therefore, the Secretary could not have made the necessary finding on the information before the agency. *See Alexandria Hospital v. Heckler*, 586 F. Supp. 581, 589 (E.D. Va. 1984) (neither Westat report nor any evidence in rulemaking record supports Secretary's conclusion that supposed disproportionate allocation of malpractice costs is so great as to defeat the operation of the G&A pool's averaging principle).

The Secretary's action in removing malpractice insurance costs from the G&A pool is particularly suspect in light of the agency's long-standing resistance to providers' attempts to isolate other costs disproportionately attributable to Medicare and thus under-reimbursed under the pooling system. *See* PRRB Decision No. 79-D53, 1979-2 Medicare & Medicaid Guide (CCH) ¶ 30,086, at 9707 ("Program policy has consistently maintained that it is impractical to isolate discrete items of [G&A] cost between Medicare and non-Medicare beneficiaries and has posited that all such discrete items making up total [G&A] costs will 'average out.' "); *Good Luck Nursing Home, Inc. v. Califano*, 1979-1 Medicare & Medicaid Guide (CCH) ¶ 29,450, at 9287 (D.D.C. 1978) (finding arbitrary and capricious the PRRB's refusal to remove from the G&A pool certain legal and accounting fees incurred solely as a result of provider's participation in Medicare program); PRRB Decision No. 76-D74, 1976 Medicare & Medicaid Guide (CCH) ¶ 28,300, at 10,609-10 (refusing to remove from G&A pool certain extraordinary legal fees attributable solely to Medicare program); Provider Appeal Decision No. 00-75-04, 1975 Medicare & Medicaid Guide (CCH) 27,361, at 9589 (refusing to remove from the G&A pool certain expenses incurred in preparing Medicare cost reports); Intermediary Letter No. 234 (June 2, 1967) (including in G&A pool all costs of Medicare utilization review, including compensation paid to physicians for their services on utilization review committees). The agency has long believed that

> [t]he requirement in the law that our costs are not to be borne by others is construed to refer to *total* costs,

> not to any one cost. In our cost finding procedures . . . it is presumed that where a particular cost might be allocated disproportionately to or from the program, there will be other costs disproportionately allocated in the other direction which will compensate for the first cost. In this manner, the program is presumed to bear its proper share of the total allowable costs.

Intermediary Letter No. 234 (June 2, 1967). The agency continues to hold this view with respect to G&A costs other than malpractice insurance premiums. *See* PRRB Decision No. 82-D46, 1982 Medicare & Medicaid Guide (CCH) ¶ 31,810, at 9073.

Although an agency is not rigidly bound to its own precedent, the presumption is against changes in established policy that are not justified by the rulemaking record. *See Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 103 S. Ct. 2856, 2866 (1983). We conclude that the Secretary violated the cost-shifting prohibition of the Medicare Act by removing malpractice insurance costs from the G&A pool without first determining, on the basis of an adequate factual record, that the existing system itself inequitably shifted costs and that removal of malpractice costs from the pool would rectify the inequity.

A second way in which the Malpractice Rule violates the Medicare Act is its failure to recognize that malpractice insurance protects against the risk of future loss. Even if a provider has never incurred any actual malpractice losses, for example, it must still purchase malpractice insurance because of the risk that losses will be incurred in the future. The Provider Reimbursement Manual recognizes this reality and thus provides that hospitals are expected to maintain an adequate insurance program to protect against likely losses, particularly losses so great that their financial stability would be threatened. *See also* PRRB Decision No. 82-D89, 1982 Medicare & Medicaid Guide (CCH) ¶ 31,987, at 9814 (malpractice insurance carried by provider to protect its assets). Providers may

and affirm the district courts' grant of summary judgment to the plaintiff hospitals.[9]

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Clerk of the United States Court of Appeals for the Seventh Circuit

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[9] We must remand No. 84-1727, the Humana case, for clarification of the district court's disposition of two claims raised by Humana in addition to its attack on the Malpractice Rule. Humana's additional claims are: (1) that the Secretary's regulations are contrary to the Medicare Act because they do not provide for a procedure by which the Secretary can make "suitable retroactive corrective adjustments to a provider's reimbursement" whenever a provider's reimbursement under the Malpractice Rule is shown to be inadequate, as required by the Act (42 U.S.C. § 1395x(v)(1)(A)(ii) (1982)), and (2) that four categories of costs attributable solely to its Medicare program should be removed from the G&A pool and fully reimbursed by Medicare. The district court simply issued a one-page order adopting Judge Will's opinion in *St. James Hosp. v. Heckler*, 579 F. Supp. 757 (N.D. Ill. 1984) (holding Malpractice Rule invalid), and did not address these additional issues. *Humana of Illinois, Inc. v. Heckler*, 584 F. Supp. 618, 619 (C.D. Ill. 1984).

Because we affirm the district court's decision that the Malpractice Rule is invalid, we do not address these two additional claims against the Secretary on appeal. *See Humana of Aurora, Inc. v. Heckler*, 753 F.2d 1579, 1583 (10th Cir. 1985) (declining to reach hospital's claim for full reimbursement of other G&A costs in light of conclusion that Malpractice Rule invalid). The court's blanket grant of summary judgment to Humana, however, seems to enter judgment for Humana on its two additional claims, including its claim for $8,459 on the ground that other G&A costs should be removed from the G&A pool and reimbursed fully. We suspect that this was not the court's intent, and therefore remand this portion of the case to the district court for clarification.

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APPENDIX B

UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

No. 84-1478

ST. JAMES HOSPITAL, PLAINTIFF-APPELLEE,

vs.

MARGARET M. HECKLER, SECRETARY OF HEALTH & HUMAN SERVICES, DEFENDANT-APPELLANT.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.
No. 83 C 2773—Judge Hubert L. Will

No. 84-1727

HUMANA OF ILLINOIS, INC., d/b/a SPRINGFIELD COMMUNITY HOSPITAL, PLAINTIFF-APPELLEE,

vs.

MARGARET M. HECKLER, SECRETARY OF HEALTH & HUMAN SERVICES, DEFENDANT-APPELLANT.

Appeal from the United States District Court for the Central District of Illinois, Springfield Division.
No. 83 C 3061—Judge J. Waldo Ackerman

April 18, 1985

Before
Hon. WILLIAM J. BAUER, *Circuit Judge*
Hon. JOEL M. FLAUM, *Circuit Judge*
Hon. ROBERT A. GRANT, *Senior District Judge**

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* The Honorable Robert A. Grant, Senior District Judge for the Northern District of Indiana, is sitting by designation.

JUDGMENT—ORAL ARGUMENT

This cause was heard on the records from the United States District Courts for the Northern and Central Districts of Illinois, and was argued by counsel.

On consideration whereof, IT IS ORDERED AND ADJUDGED by this Court that the judgment of the District Court for the Northern District of Illinois in Appeal Number 84-1478 is hereby AFFIRMED, with costs, in accordance with the opinion of this Court filed this date.

On consideration whereof, IT IS FURTHER ORDERED AND ADJUDGED by this Court that the judgment of the District Court for the Central District of Illinois in Appeal Number 84-1727 is hereby AFFIRMED IN PART, with costs, and REMANDED IN PART, in accordance with the opinion of this Court filed this date.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

No. 83 C 2773

ST. JAMES HOSPITAL, PLAINTIFF,

v.

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, DEFENDANT.

[Filed: Jan. 27, 1984]

MEMORANDUM OPINION

In this action, plaintiff, a provider of services under Part A of the Medicare program, 42 U.S.C. § 1395(x)(u), challenges an administrative regulation, 42 C.F.R. § 405.452(b)(1)(ii)[1], which alters the compu-

[1] 42 C.F.R. § 405.452(b)(1)(ii) provides:

(1) *Exception:* For cost reporting periods beginning on or after July 1, 1979, costs of malpractice insurance premiums and self-insurance fund contributions must be separately accumulated and directly apportioned to Medicare. The apportionment must be based on the dollar ratio of the provider's Medicare paid malpractice losses to its total paid malpractices losses for the current cost reporting period and the preceding 4-year period. If a provider has no malpractice loss experience for the 5-year period, the costs of malpractice insurance premiums of self-insurance fund contributions must be apportioned to Medicare based on the national ratio of malpractice awards paid to Medicare beneficiaries to malpractice awards paid to all patients. The Health Care Financing Administration will calculate this ratio periodically based on the most recent departmental closed claim study.

If a provider pays allowable uninsured malpractice losses incurred by Medicare beneficiaries, either through allowable deductible or coinsurance provisions, or as a result of an award in excess of reasonable coverage limits, or as a governmental provider, such losses and related direct costs must be directly assigned to Medicare for reimbursement.

tation formula, in effect since the inception of the Medicare program in 1966, used to reimburse provider hospitals for the costs of malpractice insurance. Before us are plaintiff's and defendant's cross-motions for summary judgment and defendant's motion to strike plaintiffs' affidavits in Attachment C to its complaint for declaratory and injunctive relief and sums due under the Medicare statute. For the reasons hereinafter stated:

(1) plaintiff's motion for summary judgment is granted;

(2) defendant's motion for summary judgment is denied;

(3) the matter is remanded to the Secretary for further consideration in accord with this opinion; and

(4) we grant defendant's motion to strike that portion of Attachment C, namely Vol. II, which contains the affidavits of "expert witneses".

I.

As a participant in the Medicare program, a hospital must file a "provider agreement" with the Secretary of Health and Human Services, 42 U.S.C. § 1395cc, under which it agrees not to charge any Medicare patient for services covered by the Medicare program, in return for reimbursement by the program of the "reasonable cost" of such services. 42 U.S.C. § 1395f(b)(1)(A). Payment to providers of services is made directly or through fiscal intermediaries, such as Blue Cross/Blue Shield pursuant to contract with the Secretary. 42 U.S.C. § 1395h. After the close of its fiscal year, a provider submits a "cost report" reflecting costs incurred during the fiscal year and an apportionment of those costs between Medicare and non-Medicare patients. 42 C.F.R. §§ 405.406(b), 405.453(f).

In its complaint, filed April 21, 1983, plaintiff challenges the intermediary settlement of its cost year ending in 1980. During that cost year, plaintiff had a provider agreement with the Secretary for the provision of

Medicare services. Prior to the challenged regulation, plaintiff was reimbursed for its malpractice premium costs on the basis of Medicare utilization of services, which was approximately 30 percent for the cost year in issue. However, the fiscal intermediary determined reimbursement for plaintiff's malpractice costs for that cost year on the basis of the challenged malpractice apportionment regulation, rather than on the former basis of utilization. This resulted in reimbursement of only 20.11 percent of plaintiff's malpractice insurance costs. At issue is $24,159 in denied Medicare reimbursement; allegedly the difference in sum between the reimbursement of 20.11 percent and the Medicare utilization rate of 30 percent for the cost year in issue.

On June 3, 1981, plaintiff, together with many Florida hospitals and one Alabama hospital, requested a group hearing before the Provider Reimbursement Review Board ("PRRB") pursuant to 42 U.S.C. § 1395oo(a), appealing the malpractice insurance costs allowed in its Notice of Program Reimbursement, and thus challenging the legality of the malpractice regulation. The PRRB decided that it lacked authority to determine whether the Medicare regulation governing reimbursement for malpractice insurance, 42 C.F.R. § 405.452(b)(1)(ii) (June 1, 1979), is valid, found that the case falls within 42 U.S.C. § 1395oo(f)(1), and granted the providers' requests for an expedited judicial review of the malpractice insurance issue. Thus, this case is before us pursuant to 42 U.S.C. § 1395oo which states in relevant part:

> Providers shall also have the right to obtain judicial review of any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the Board determines . . . that it is without authority to decide the question. . . .

II.

We are not the first court confronted with the issue of the validity of the new malpractice regulation. To date, seven courts have ruled on this matter. Three courts have invalidated the regulation. *See Mt. Carmel Mercy Hospital* v. *Margaret M. Heckler*, No. 82-74193 (E.D. Mich. Nov. 30, 1983) (J. DeMascio); *Abington Memorial Hospital* v. *Margaret M. Heckler*, No. 82-2856 (E.D. Pa. Dec. 8, 1983) (J. Fullam); *Chelsea Community Hospital* v. *Margaret M. Heckler*, No. 83CV-6126-AA (E.D. Mich. Dec. 20, 1983) (J. Joiner). Four courts have upheld the regulation. *See Athens Community Hospital* v. *Heckler*, 565 F. Supp. 695 (E.D. Tenn. May 31, 1983) (J. Taylor), *appeal docketed*, No. 83-5546 (6th Cir. Aug. 5, 1983); *Cumberland Medical Center* v. *Heckler*, No. 82-2121 (M.D. Tenn. June 22, 1983) (J. Morton), *appeal docketed*, No. 83-5549 (6th Cir. Aug. 9, 1983); *Humana of Aurora, Inc, d/b/a/ Aurora Community Hospital* v. *Heckler*, No. 83-Z-70 (D. Colo. Sept. 19, 1983) (J. Weinshienk), *appeal docketed*, No. 83-2417 (10th Cir. Nov. 4, 1983); *Walter O. Boswell Memorial Hospital* v. *Heckler*, 573 F. Supp. 884 (D.D.C. Sept. 27, 1983) (J. Bryant), *appeal docketed*, No. 83-2223 (D.C. Cir. Dec. 2, 1983). Four substantive opinions have been written; Judges Fullam and DeMascio have invalidated the malpractice rule and Judges Taylor and Bryant have upheld the rule.[2] Because these courts have well-described the basic facts concerning the malpractice regulation, we shall not belabor the story. However, in the interests of clarity, we

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[2] In *Chelsea*, Judge Joiner adopted Judge DeMascio's opinion in *Mt. Carmel*. Similarly, in *Cumberland*, Judge Morton followed Judge Taylor's opinion in *Athens*. Judge Weinshienk issued her opinion from the bench and no written opinion will be issued. *Humana* Tr. at 56.

will briefly sketch the undisputed facts underlying this action.

III.

Prior to the challenged regulation, effective July 1, 1979, malpratice insurance costs were included in the "General and Administrative" category ("G&A") of hospital expenses, along with other insurance costs and such costs as administrative salaries. To apportion G&A between Medicare and non-Medicare patients, Medicare reimbursed hospitals for the costs of malpractice insurance based upon the ratio of Medicare patient utilization of the hospital's services to total patient utilization—the percentage of patient bed-days used by Medicare patients. The effect of this, albeit simplified, is that prior to July 1, 1979, if a hospital's services were utilized "x" percent by medicare patients, the hospital would be reimbursed "x" percent of its malpractice insurance premium costs by the Medicare program.[3]

In contrast, effective July 1, 1979, the challenged malpractice rule reimburses a hospital for that percentage of it malpractice insurance costs equal to the ratio of malpractice losses it has paid to Medicare beneficiaries to total malpractice losses paid to all patients during the current and four preceding years. 42 C.F.R. § 405.452(b)(1)(ii). Further, hospitals with no malpractice loss experience for the five-year period will be reimbursed for only 5.1 percent of their insurance costs for the year.[4]

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[3] This was done pursuant to 42 U.S.C. § 1395x(v)(1)(A)(1979) which allows for payment of "reasonable cost" of the services, which is defined as "the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services."

[4] Under the proposed rule, these hospitals were to obtain from an independent actuary an estimate of Medicare's share of current malpractice costs. 44 Fed. Reg. 15744, 15745 (1979). The final rule eliminates and replaces it with a national ratio of 5.1 percent, a figure derived from data in the consultant's study cited by the Secretary. *See Abington Hospital, supra*, slip op. at 3-4.

The effects of the final rule differ markedly from the previous rule. For example, if a hospital's insurer has paid $100,000 to Medicare claimants and $200,000 to non-Medicare claimants during the five-year period, the hospital would be reimbursed for one-third of its malpractice insurance costs for the current year.

Plaintiff offers an example of the impact of the regulation on a hypothetical hospital with a 60 percent Medicare utilization rate and malpractice insurance premiums of $100,000 per year. Under the prior regulation, Medicare would have reimbursed this hypothetical hospital approximately $60,000 for its malpractice insurance premium costs. Under the challenged regulation, reimbursement would occur as follows:

> (1) If the hospital, during the relevant five-year period specified by the challenged regulation, pays only one malpractice claim, no matter what the amount, to a Medicare recipient, Medicare will reimburse the hospital $100,000 or 100% of its malpractice insurance costs;
>
> (2) If, instead of paying a single malpractice claim to a Medicare recipient, the same amount is paid as the result of a claim by a non-Medicare recipient, Medicare will reimburse the hospital *none* of its malpractice insurance costs;
>
> (3) If the hospital makes no payments on malpractice claims during the relevant five-year period, Medicare will reimburse the hospital only $5,100, or 5.1% of its malpractice insurance costs.

Pl. Br. at 3. The Secretary says these examples are "patently ludicrous" and "extreme", and that the new formula represents a fair estimate of Medicare's share of the risk. Def. Br. at 32-33. However, we find that under the very terms of the challenged regulation the reimbursements to the hypothetical hospital cited by plaintiff would be as plaintiff posits. *See Mt. Carmel Mercy Hospital, supra*, slip op. at 16 ("This national ratio completely ignores the risk element of insurance....

[The examples] show that it is merely fortuitous whether a hospital is properly reimbursed for its malpractice insurance costs."); *Abington Memorial Hospital, supra,* slip op. at 14.

IV.

Before we address plaintiff's procedural and substantive challenges to the regulation, we must, as a preliminary matter, decide the issues raised by the Secretary's motion to strike plaintiff's affidavits in Attachment C to its complaint. We previously denied the Secretary's motion to dismiss this action or, alternatively, to strike all attachments and those portions of the complaint referring to the attachments. We instructed her to answer, but did not require her to plead to the attachments in her answer. Mem. Op. (Sept. 19, 1983). For purposes of her present motion to strike certain portions of Attachment C, the issues command a different result.

The affidavits in issue here are from James P. Bedingfield, an Associate Professor of Accounting and Certified Public Accountant, Edward D. Hollander, a consulting economist with expertise in health economics and health insurance, W. James MacGinnitie, an actuary with extensive experience in the area of medical malpractice insurance, Douglas G. Olson, an Associate Professor of risk management, insurance, and health care systems, and David D. Willman, a Certified Public Accountant. These five affidavits were filed with the PRRB and, in part, form the basis for plaintiff's challenge to the Westat study, upon which the Secretary relied in drafting the new regulation.

The Secretary contends that none of these affidavits are part of the rulemaking record and thus they should be stricken. She is correct. It is well-settled that a reviewing court is required to "review the whole record" in determining the validity of a regulation, 5 U.S.C. § 706, and that the "whole record" consists solely of the

administrative rulemaking record. *Camp* v. *Pitts*, 411 U.S. 138, 142 (1973); *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 419, 420 (1971). Litigation affidavits, such as those presented by plaintiff, are merely "*post hoc*" rationalizations and do not constitute the "'whole record' compiled by the agency...." *Overton Park, supra*, at 419 (citations omitted).

Plaintiff contends that the proffered affidavits (1) set forth basic accounting principles available to the agency during the rulemaking and (2) in part merely retabulate the actual Westat data which the agency used as the basis for the rule. But this does not satisfy the requirement of being the "whole record" before the agency.

Alternatively, plaintiff urges that we may consider these affidavits, though outside the administrative record, based on certain exceptions; if the materials postdating the rule (1) clarify or explain the original information before the agency, *Association of Pacific Fisheries* v. *EPA*, 615 F.2d 794, 811 (9th Cir. 1980); or (2) show that the agency's assumptions were fictional or without scientific support, *id.*; or (3) will assist the court in determining whether the agency considered all the relevant factors. *Environmental Defense Fund, Inc.* v. *Costle*, 657 F.2d 275, 285 (D.C. Cir. 1981).

We are not persuaded by plaintiff's suggestions. Indeed, in *Environmental Defense Fund, supra*, at 285-286, cited by plaintiff, the District of Columbia Circuit Court found that the motion to strike litigation affidavits of affiants who were neither employees of EPA nor participants in the agency actions to have been properly granted. *See also Asarco, Inc.* v. *EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980), also cited by plaintiff ("[W]e think the district court went too far in its consideration of evidence outside the administrative record.") Presented with similar matter, Judge Fullam found that the lengthy affidavits detailing additional flaws in

the Westat study were not properly before the court. *Abington Memorial Hospital, supra,* slip op. at 11, n.4. Persuaded by the reasoning of these courts and convinced that the voluminous briefs and the rulemaking record properly before this court furnish more than adequate information about the validity and reliability of the Westat study without these litigation affidavits, we grant defendant's motion to strike plaintiff's affidavits in Attachment C.

V.

We now turn to plaintiff's procedural and substantive attacks on the malpractice rule. Our inquiry concerning the validity of the rule must focus on whether the Secretary acted within the scope of her statutory power, whether the actual choice made was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law", and whether the Secretary complied with the necessary procedural requirements in promulgating the rule. *Overton Park, supra,* 401 U.S. at 416-417.

We recognize that the standard of review of an agency's decision is a narrow one; "[t]he court is not empowered to substitute its judgment for that of the agency." *Id.* at 416. However, the judicial deference usually afforded to an agency's determination of how best to achieve statutory policies enacted by Congress "cannot be allowed to slip into judicial inertia," *Bureau of Alcohol, Tobacco and Firearms* v. *Federal Labor Relations Authority,* 104 S.Ct. 439, 444 (1983); *American Ship Building Co.* v. *NLRB,* 380 U.S. 300, 318 (1965). Courts "are not obliged to stand aside and rubberstamp their affirmance of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *NLRB* v. *Brown,* 380 U.S. 278, 291 (1965). Moreover, "[i]f Congress established a presumption from which judicial review should start, that presump-

tion . . . [is] *against* changes in current policy that are not jusitified by the rulemaking record." *Motor Vehicle Manufacturers Association, of the United States, Inc.* v. *State Farm Mutual Automobile Insurance Co.*, 103 S.Ct. 2856, 2866 (1983) (emphasis in original). With these considerations in mind, we address the merits of plaintiff's challenge to the rule.

Notice

Plaintiff first contends that the agency failed to comply with the procedural requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553, in that it (1) failed to issue a sufficient notice of the rulemaking and (2) failed to provide an adequate basis and purpose statement with the malpractice regulation.

The test of the adequacy of a Notice of Proposed Rulemaking ("NPRM") is whether it "fairly apprise[d] interested parties of all significant subjects and issues involved." *American Iron and Steel Institute* v. *EPA*, 568 F.2d 284, 291 (3d Cir. 1977), *cert. denied*, 435 U.S. 914 (1978) (citations omitted). Plaintiff claims that the Notice was deficient as it referred only to a "study conducted by a HEW consultant", rather than identifying the Westat study by name. (However, the final rule did identify the report's author as Westat, Inc., *see* 41 Fed. Reg. 31641 (June 1, 1979).) Plaintiff contends that this "suppression" of information was an attempt to discourage comment on those aspects of the study in which the study's authors question the reliability and sample adequacy of the study itself, Pl. Ex. 22, and the "suppression" was further compounded by the agency's initial attempt to provide only a 45-day notice period, despite the 60-day requirement of Executive Order 12044. However, the agency subsequently extended the notice period to 60 days.[5]

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[5] There is some evidence that the Secretary, under budgetary pressures and deadlines, did engage in the administrative version

It is important for "[a]n agency to identify and make available technical studies and data that it has employed in reaching the decision to propose particular rules." *Connecticut Light and Power Co.* v. *Nuclear Regulatory Commission*, 673 F.2d 525, 531 (D.C. Cir.), *cert. denied*, 103 S.Ct. 79 (1982). While the agency here technically did not fully comply with this requirement, the record shows that although the Westat study was not widely distributed throughout the health care community, several major health care organizations such as the American Hospital Association, the Hospital Corporation of America, and the Federation of American Hospitals[6] received the consultant's report in time to review it before submitting comments criticizing the statistical validity of the Westat study. Thus we agree with those courts that have considered plaintiffs' attack on the sufficiency of notice and found that the notice was sufficient fairly to apprise the interested parties. *See Abington Memorial Hospital, supra*, slip op. at 6-7; *Athens Community Hospital, supra*, 565 F. Supp. at 698; *Walter O Boswell Memorial Hospital*, 573 F. Supp. at 889-890.

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of the football "hurry-up offense". *See, e.g.*, 44 Fed. Reg. at 15745 (Mar. 15, 1979) (intially allowing only 45 days for comment); Pl. Ex. 13, Mem. from Regulation Coordination branch (Feb. 16, 1979) ("Because of the urgency (to meet budget commitments) we are requesting concurrent HFCA and OS review in a very short turn around (2/22). If major issues are raised, a policy meeting will be scheduled. The goal is to publish a final regulation by July 1, 1979."); Pl. Ex. 13 at 4, Mem. to Secretary from Administrator, Health Care Finance Administration ("*Urgency* [:] Since final regulations establishing new apportionment procedure must be effective for part of the FY 1979 if the HFCA budget is to be met, the Notice of Proposed Rulemaking must be published as soon as possible....")

[6] These organizations represent 6400, 120, and 1000 hospitals respectively. *Abington Memorial Hospital, supra*, slip op. at 6.

Basis and Purpose

The second prong of plaintiff's procedural attack under 5 U.S.C. § 553 is that the agency failed to provide an adequate basis and purpose statement with the malpractice regulation and failed to respond adequately to the uniformly negative public comments on the proposed rule. We believe that plaintiff's contention is correct—the agency failed to meet the standards provided by the statute and articulated by the courts.

Section 553(c) provides in relevant part:

> (c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. . . .

It is clear that the statute requires an agency to *consider* the relevant matter and comments presented and to *incorporate* a concise general statement of their basis and purpose, for "the opportunity to comment is meaningless unless the agency responds to significant points raised by the public." *Home Box Office, Inc.* v. *FCC*, 567 F.2d 9, 35 (D.C. Cir.), *cert. denied*, 434 U.S. 829 (1977).

The Secretary contends that the agency complied with the "basis and purpose" statement in its concise articulation published with the regulation in 44 Fed. Reg. 31641-42. But, as Judge Fullam notes:

> It would have been a miracle of bureaucratic succinctness had the Secretary managed to reply adequately in two scant columns of Federal Register prose to the 600-plus comments that occupy five thick volumes of the administrative record. Unfortunately, no such miracle has been witnessed by

this court, which instead finds the Secretary's response woefully inadequate.

Abington Memorial Hospital, supra, slip op. at 8.

Judge Fullam found particularly disturbing, as do we, the complete lack of response to numerous comments challenging the statistical validity of the Westat study, the sole empirical study on which the change in malpractice reimbursement was based. While the discussion of major comments purportedly responded to "the most significant comments"—(1) opposition to the direct apportionment of malpractice costs; (2) direct assignment of overhead costs; (3) cash flow; and (4) claims management—44 Fed. Reg. 31641-42, the discussion did not address whether commentators criticized the Westat report nor adequately respond to those criticisms. Also absent is any mention of Westat's written comments to the agency which cautioned that it was "virtually impossible to generalize beyond the sample" and that "there was no assurance that the sample was in any way representative", *see* Pl. Ex. 22 at 2 ¶ A, and cautionary comments within the study itself. *See, e.g.*, Pl. Ex. 21 at 2-9 (Westat study) ("Because the data base consists of a census of claims closed by nine private insurance carriers during a four month period in 1976, it is not altogether clear what constitutes the universe of claims from which this 'sample' was drawn. It seems proper, since this is a census, to make inferences only within the time frame for which the data were collected and only to the universe of claims closed by nine participating companies."); Pl. Ex. 21 at 2-1 ("The sample was judgmental, rather than a probability sample....")

That the Secretary "proceeded to promulgate a final rule even though the comments were unanimously in opposition, does not [in itself] prove that the Secretary failed to consider the comments." *Boswell, supra*, 573 F. Supp. at 890. However, "where apparently significant information has been brought to its attention

[here, *e.g.*, the comments within the Westat study itself, the post-study comments by Westat people, and objections to the study raised by several major health care groups] or substantial issues of policy or gaps in its reasoning raised, the statement of basis and purpose must indicate why the agency decided the criticisms were invalid." *National Resources Defense Council, Inc.* v. *U.S. Nuclear Regulatory Commission*, 547 F.2d 633, 646 (D.C. Cir. 1976), *rev'd on other grounds by Vermont Yankee Power Corp.* v. *Natural Resources Defense Council, Inc.*, 435 U.S. 519 (1978).

The notice and purpose statement in 44 Fed. Reg. 31641 fails to reflect the requisite exchange of views, information, and response to criticism; the agency failed to respond to significant points raised by the public. *See Home Box Office, Inc.* v. *FCC*, 567 F.2d 9, 35-36 (D.C. Cir.), *cert. denied*, 434 U.S. 829 (1977), *reh. denied*, 434 U.S. 988 (1977). Absent from the statement are comments reflecting the "philosophy of candor" which must characterize a basis and purpose statement. *See* J. Wright, The Courts and The Rulemaking Process: the Limits of Judicial Review, 59 Cornell L. Rev. 375, 381 (1979). The record shows that the agency's general counsel had "technical problems" with the Final Regulations. *See* Pl. Ex. 20, Note from HEW, Office of the General Counsel (May 18, 1979) ("We do not believe that the preamble is adequate. Nor do we believe it is clearly written. HFCA received some 450 public comments on the NPRM. All of the public comments opposed the proposed regulation. Therefore we believe that HFCA needs to carefully explain why it is rejecting the public comments.") Given all this, we conclude that the agency failed to comply with section 553(c) of APA.

Arbitrary and Capricious

Plaintiff further contends that the promulgation of the malpractice regulation, 20 C.F.R. § 405.452(i)(ii), is

violative of APA, 5 U.S.C. § 706(2)(A), which requires a reviewing court to hold unlawful and set aside agency action found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. In this regard, we reiterate that our standard of review here is a narrow one, but "[j]udicial review in accordance with this standard is not toothless...." *City of West Chicago* v. *U.S. Nuclear Regulatory Commission*, 701 F.2d 632, 648 (7th Cir. 1983). By conducting a searching and careful inquiry into the facts, the court must consider whether the agency's decision was based on consideration of the relevant factors and whether there has been a clear error of judgment. *Overton Park*, *supra*, 401 U.S. at 416, and whether the agency has articulated a rational connection between the facts found and the choice made. *Baltimore Gas & Electric Co.* v. *Natural Resources Defense Council, Inc.*, 103 S.Ct. 2246, 2257 (1983).

The Secretary claims that the malpractice rule is a logical response to an immediate and serious problem—Medicare paying an allegedly disproportionate amount of malpractice costs under the prior program. The Secretary's, as well as the entire nation's, concern with the ever-escalating costs of Medicare, and indeed the entire social security program, and fear of financial insolvency is not unfounded. Nor does her concern with budgetary considerations evidence an arbitrary and unreasoned approach to a very serious problem. But this does not end our inquiry. Although "an agency must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances,'" *Motor Vehicle*, *supra*, 103 S.Ct. at 2866, the scope of our review does not change. *Id.*

An agency's rule is arbitrary and capricious if (1) the agency relied on factors which Congress had not intended it to consider; (2) the agency entirely failed to consider an important aspect of the problem; (3) if it of-

fered an explanation for its decision that runs counter to the evidence before the agency or is so implausible that it could not be attributed to a difference in view or the product of agency expertise. *Id.* at 2867.

With these guidelines in mind, we agree with Judges Fullam and DeMascio that the rule is arbitrary and capricious. There are several reasons why the rule cannot pass judicial muster. First, the Westat study furnishes an inadequate basis for the rule as we previously noted in our discussion of the agency's compliance with the "basis and purpose" statement. In fact, the authors of the Westat study cautioned against extrapolation of wide-ranging conclusions and noted that "conclusions must be drawn very cautiously because of the possibility of biased data." *See* Westat Report at 2-3 (Pl. Ex. 21, Def. Ex.C). The authors note two potential sources of bias in the sample of claims. First, many claims had multiple defendants who were not always represented by participating companies and although reporting companies probably knew the total number of defendants "they could not provide us with specific information about their characteristics." *Id.* at 2-2. The second potential source of bias is that some providers, especially hospitals, are self-insuring and thus their claims had "no chance of turning up in the data base." *Id.*

In *Almay, Inc.* v. *Califano*, 569 F.2d 674, 677, 682 (D.C. Cir. 1977), the court considered whether the FDA's reliance on a "flawed survey", about which the Director of FTC's Bureau of Consumer Protection who sponsored and designed the study warned that the results should be used with caution, constituted a violation of the arbitrary and capricious standards of 5 U.S.C. § 702(2)(A). The court held that reliance on the survey was a "'clear error of judgment.'" *Id.* at 682 (citation omitted). In the present case, reliance on the Westat study is similarly an error in judgment.

The other grounds upon which plaintiff relies in terming the rule arbitrary and capricious, including that the rule impermissibly shifts costs of care for Medicare patients to non-Medicare patients, are the same grounds on which it challenges the regulation as violative of the Medicare statute, 42 U.S.C. § 1395, *et seq.*, and thus we shall now address that contention.

Violation of the Medicare Statute

The Medicare statute under which the agency promulgated the rule states that a provider hospital shall be reimbursed "[t]he reasonable cost of any services [which] shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services. . . ." 42 U.S.C. § 1395x(v)(1)(A). To be valid, therefore, the regulation must take into account both a provider's direct and indirect costs, and may not cause costs properly allocable to care of Medicare patients to be shifted to non-Medicare patients. *Id; Northwest Hospital, Inc.* v. *Hospital Service Corp.* 687 F.2d 985, 989 (7th Cir. 1982). Further, the cost regulation must be rational, non-arbitrary and must further the purposes of the Medicare statute. *Northwest* at 989. Plaintiff contends that the regulation falls far short of this standard because it fails to reimburse provider hospitals for insurance costs reasonably incurred in treating Medicare patients.

The statute affords the Secretary some discretion in prescribing regulations that determine the computation of the reasonable cost of services. But her discretion is not unlimited and certainly not beyond judicial review. We would not, of course, substitute our judgment for that of the Secretary, but if her interpretation of reasonable cost does not comport with statutory requirements then it should not be upheld. We cannot "rubberstamp" administrative decisions that are inconsistent

with statutory mandates. *See Bureau of Alcohol, Tobacco, and Firearms* v. *FLRA*, *supra*, 104 S.Ct. at 444.

Prior to the challenged regulation, the Secretary had aggregated all general and administrative ("G&A") costs, including malpractice insurance. Plaintiff argues that there is no logical reason to separate malpractice insurance from other insurance and other G&A costs. By so doing, the Secretary ignores the fact that insurance premiums are paid regardless of whether actual losses are incurred or not, and that malpractice insurance is designed to protect, necessarily, the assets of a hospital against potential catastrophic loss. *See Mt. Carmel*, *supra*, slip op. at 10.

Earlier in this opinion we discussed the effects of the new regulation on hospital malpractice reimbursement. These effects prompted Judge Fullam to observe that the Secretary has chosen "an allocation formula which is least likely to reflect reality . . . a formula which seemingly guarantees that the statutory mandate will inevitably be violated in most cases." *Abington Memorial Hospital*, *supra*, slip op. at 16. This is so because:

> (1) the ratio between malpractice claims paid on account of Medicare patients and malpractice claims paid on account of non-Medicare patients over the most recent five-year period has very little, if any, relationship to the hospital's current cost of maintaining malpractice protection. (2) The "national average" (currently estimated at 5.1%) of that ratio has even less bearing on the current malpractice coverage costs of any particular hospital. (3) The data relied upon in the Westate Report, including the data which produced the 5.1% figure, included both payments made to satisfy the liability of hospitals and claims paid to satisfy the liability of physicians. There is no evidence to support the conclusion that these combined payments provide reliable information about the malpractice

> payment experience of hospitals. Indeed, there is reason to believe that they do not....

Id. at 16-17.

We emphasize that the Secretary is not, of course, limited to any one method of reimbursement and may use different methods for different costs and circumstances. This the statute clearly allows. 42 U.S.C. § 1395x(v)(1)(A). But when, as here, the chosen method neither assures that Medicare costs will not be borne by non-Medicare patients nor that hospitals will be reimbursed the reasonable costs of their services ("actual costs minus those found to be unnecessary in the efficient delivery of health services") then the regulation does not carry out the mandate of the Medicare statute and is invalid.

Conclusion

For the reasons stated above, the defendant's motion to strike affidavits in Attachment C of the complaint is granted. Defendant's motion for summary judgment is denied. Plaintiff's motion for summary judgment is granted. The agency failed to provide an adequate basis and purpose statement. The regulation is arbitrary and capricious and does not comport with the requirements of the Medicare statute. The matter is remanded to the Secretary for further consideration in accord with this opinion.

ENTER:

/S/ Hubert L. Will
United States District Judge

DATED: JANUARY 27, 1984

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF ILLINOIS—
SPRINGFIELD DIVISION

No. 83-3061

HUMANA OF ILLINOIS, INC.
d/b/a SPRINGFIELD COMMUNITY HOSPITAL,
PLAINTIFF,

v.

MARGARET M. HECKLER, DEFENDANT.

[Filed: Mar. 2, 1984]

ORDER

This matter is before the Court on the parties' cross-motions for summary judgment. On October 14, 1983, the Court heard oral arguments on the motions. Since that time, numerous district courts throughout the country, including the Honorable Hubert L. Will in the Northern District of Illinois, have ruled on the questions raised by the Plaintiffs in this action. After a review of the briefs and arguments by the respective parties in this action, and a review of the decisions recently rendered by the various district courts throughout the country who have confronted these identical questions, it is my opinion that the regulation promulgated by the Department of Health and Human Services was arbitrary and capricious and does not comport with the requirements of the Medicare statute. In support of this decision, I adopt the opinion of Judge Will in *St. James Hospital* v. *Heckler*, No. 83-2773 (N.D. Ill. Jan. 27, 1984). As I do not believe that I could add anything

substantial to the already well-reasoned decisions of the other district judges in this country, I will not render an additional written decision.

Therefore, Plaintiffs' motion for summary judgment is granted; Defendant's motion for summary judgment is denied.

Enter this 1st day of March 1984.

/s/ J. Waldo Ackerman
J. WALDO ACKERMAN
Chief U.S. District Judge

APPENDIX E

44 Fed. Reg. 31641 (1979)

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE

Health Care Financing Administration

42 CFR Part 405

Principles of Reimbursement for Provider Costs and for Services by Hospital-Based Physicians; Direct Apportionment of Malpractice Costs to Medicare

AGENCY: Health Care Financing Administration (HCFA), HEW.

ACTION: Final rule.

SUMMARY: This amendment requires malpractice costs incurred by a provider to be directly apportioned to Medicare based on Medicare malpractice loss experience, instead of the current apportionment basis of Medicare's overall utilization of provider services. It requires a separate accumulation and direct apportionment of malpractice insurance premiums and self-insurance fund contributions. In addition, when a provider pays allowable uninsured malpractice losses incurred by Medicare beneficiaries, as a result of the application of deductible or coinsurance provisions of a purchased insurance policy, or as a result of an award in excess of reasonable coverage limits, or as a governmental provider, Medicare will reimburse the costs of these losses and any related direct costs. The purpose is to reimburse Medicare providers on a basis more closely related to actual malpractice experience.

DATE: Effective July 1, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. Hugh McConville, (301) 594-9682.

SUPPLEMENTARY INFORMATION:

Background

Under sections 1814(b) and 1833(a)(2)(A) of the Social Security Act, providers of services are to be paid the lesser of reasonable cost of services furnished to beneficiaries or the customary charges made by the provider for the same services. Section 1861(v)(1)(A) of the Act defines reasonable cost and authorizes the Secretary to issue regulations establishing the methods to be used and items to be included in determining reasonable costs. These regulations are set forth in 42 CFR Part 405, Subpart D.

Under current regulations and other instructions issued by Medicare, malpractice costs are accumulated in the administrative and general cost center and allocated to the revenue-producing and other cost centers on the statistical basis of accumulated costs. The costs in the revenue-producing cost centers, including appropriate allocated overhead costs, are then apportioned to Medicare using the ratio of Medicare charges to total charges, or another appropriate statistical basis for ancillary and outpatient services, and the average cost per diem for Medicare beneficiaries for general routine and special care unit services.

This method results in Medicare paying a disproportionate amount of malpractice costs. A national study conducted by a DHEW consultant indicates that malpractice awards for Medicare patients are

significantly lower in amount than losses for other patient population. The lower awards for Medicare patients result because the income potential and life expectancy of these patients are less than the non-Medicare population. Thus, the use of overall Medicare utilization to allocate malpractice costs results in Medicare's paying a disproportionate amount of malpractice costs.

This amendment avoids these disproportionate payments by restructuring the cost finding and cost apportionment procedure. Costs of malpractice insurance premiums and self-insurance fund contributions will be accumulated in a specific malpractice cost center and directly apportioned to Medicare based on the provider's Medicare malpractice loss experience. The dollar ratio of malpractice losses paid for Medicare beneficiaries to total malpractice losses paid for all patients for the current cost reporting period and the preceding 4-year period will provide the basis for apportioning these malpractice costs to Medicare.

The use of an actuarial estimate when a provider has minimal malpractice losses during the 5-year period, as proposed in the Notice of Proposed Rulemaking, could also have resulted in Medicare sharing disproportionately in malpractice costs. Therefore, the final regulation has been revised to require a provider to use the national ratio of the dollar value of Medicare malpractice awards to total malpractice awards as determined by the 1976 Departmental closed claim study performed by Westat, Inc. This national ratio, as determined by the latest study, is 5.1 to 100 or 5.1 percent and is to be used instead of an actuarial estimate for apportioning malpractice insurance premiums or self-insurance fund contributions. When a provider has no malpractice loss ex-

perience for the 5-year period specified in the final regulation, Medicaid reimbursement of malpractice insurance premiums or self-insurance fund contributions would be determined by applying the national ratio of 7.5 to 100 (or 7.5 percent). This ratio was also determined by the most recent Departmental study of closed claims.

If a provider pays allowable uninsured malpractice losses for Medicare beneficiaries, as a result of the application of deductible or coinsurance provisions of a purchased insurance policy or a funded self-insurance program, or as a result of an award in excess of reasonable coverage limits, or as a governmental provider, those losses and related direct costs will be directly assigned to Medicare for reimbursement.

This regulation impacts Medicaid reimbursement because under 42 CFR 447.261(b)(2), for payment of inpatient hospital services, States participating in Medicaid must either adopt Medicare standards and principles for determining reasonable cost reimbursement as set forth in 42 CFR 405.402 through 405.455 or must meet the criteria in 42 CFR 447.261(d).

Discussion of Major Comments

A Notice of Proposed Rulemaking for this regulation was published on March 15, 1979, in the Federal Register (44 FR 15641). Comments were received from many members of the health care industry. Responses to the most significant comments are described below.

1. *Opposition to the Direct Apportionment of Malpractice Costs.* All comments received were against the proposal and recommended that we withdraw it entirely. The main argument against the proposal

was that the incurrence of malpractice costs bears no relationship to the financial class of the patient. Therefore, all patients should share equally in malpractice insurance costs or losses because these costs are incurred primarily for the benefit of the total overall patient population and for the protection of facility assets. Other arguments stressed that charges to private patients and third-party payors would necessarily increase in order to recover costs normally reimbursed by Medicare, and that additional costs for recordkeeping would be incurred.

We are aware that insurance companies generally do not determine insurance rates for malpractice insurance based upon the financial status of the patients. However, information about malpractice loss experience by type of patient (i.e., Medicare) is readily available. Moreover, this regulation is not based on a relationship between malpractice losses and the financial status of patients. As explained above, it is grounded on a direct calculation of the costs incurred in furnishing health care to Medicare beneficiaries.

We are also aware that charges to private patients and third-party payors may increase and that additional costs for recordkeeping may be incurred; we believe that this amendment is necessary in order to prevent the program from paying a disproportionate amount of substantial malpractice costs.

2. *Direct Assignment of Overhead Costs.* We received comments urging that overhead costs other than malpractice costs also be directly apportioned. We believe that the current cost finding and apportionment procedure is generally an equitable method of allocating other overhead costs. However, because malpractice costs are so significant and the dispro-

portionate allocation of malpractice costs to Medicare is so great, we believe a unique exception is warranted to deal with these costs.

3. *Cash Flow.* We received comments concerning the possibility of the apportionment ratio adversely affecting provider cash flow. If a provider pays a large dollar amount of Medicare malpractice claims in the current year and has little or no prior Medicare malpractice claim experience for the preceding 4-year period. the apportionment ratio of Medicare malpractice claim loss experience to total malpractice claim loss experience for the current period necessarily becomes smaller due to the averaging of the malpractice loss experience ratios for the entire 5-year period. Over the succeeding 5-year period, reimbursement would eventually reflect Medicare's malpractice claim experience. However, for the current year, the apportionment ratio (5-year average) would apportion to Medicare an amount less than what would have been apportioned had the current year's ratio for malpractice claim loss experience been used, thereby lowering Medicare reimbursement. Providers, therefore, would have to use their own funds until such time as Medicare reimbursement "catches up."

We wish to study this issue further, especially when circumstances are reversed and Medicare payment is greater than it might otherwise be, due to a particularly large malpractice claim in a given year. One possible solution could be a modification to 42 CFR section 405.454(h), Accelerated payments to providers, to provide relief to providers whose cash flow is adversely affected by the apportionment ratio. If so, a proposed change to this regulation section would be published in the Federal Register for comment.

4. *Claims Management.* We also received comments stating that this regulation would provide an incentive for providers to settle Medicare malpractice claims without providing the same degree of claims management as for non-Medicare malpractice claims of similar nature. We do not believe that providers would actually settle Medicare malpractice claims in such a manner. Furthermore, we do not believe that others involved in such matters, such as legal firms, insurance companies, and insurers would allow these practices. However, we will watch this carefully and take action if necessary.

EFFECTICE DATE: This amendment to the Medicare reimbursement regulations is effective for cost reporting periods beginning on or after July 1, 1979. Instructions will be provided through fiscal intermediaries for the treatment of malpractice costs for these periods and cost reporting forms will be supplied before filing.

42 CFR Part 405 is amended as follows:

1. Section 405.452 is amended by revising paragraph (b) (1) to read as follows:

§ 405.452 Determination of cost of services to beneficiaries.

* * * * *

(b) *Principle for cost reporting periods starting after December 31, 1971.* Total allowable costs of a provider shall be apportioned between program beneficiaries and other patients so that the share borne by the program is based upon actual services received by program beneficiaries. For cost reporting periods starting after December 31, 1971, the methods of apportionment are defined as follows:

(1) *Departmental Method.* (i) Except as provided in paragraph (b)(1)(ii) of this section with respect to the direct apportionment of malpractice costs, the ratio of beneficiary charges to total patient charges for the services of each ancillary department is applied to the cost of the department; to this is added the cost of routine services for program beneficiaries, determined on the basis of a separate average cost per diem for general routine patient care areas, taking into account, to the extent pertinent, an inpatient routine nursing salary cost differential (see § 405.430 for definition and application of this differential), and in hospitals, a separate average cost per diem for each intensive care unit, coronary care unit, and other special care inpatient hospital units.

(ii) *Exception:* For cost reporting periods beginning on or after July 1, 1979, costs of malpractice insurance premiums and self-insurance fund contributions must be separately accumulated and directly apportioned to Medicare. The apportionment must be based on the dollar ratio of the provider's Medicare paid malpractice losses to its total paid malpractice losses for the current cost reporting period and the preceding 4-year period. If a provider has no malpractice loss experience for the 5-year period, the costs of malpractice insurance premiums or self-insurance fund contributions must be apportioned to Medicare based on the national ratio of malpractice awards paid to Medicare beneficiaries to malpractice awards paid to all patients. The Health Care Financing Administration will calculate this ratio periodically based on the most recent departmental closed claim study.

If a provider pays allowable uninsured malpractice losses incurred by Medicare beneficiaries, either

through allowable deductible or coinsurance provisions, or as a result of an award in excess of reasonable coverage limits, or as a governmental provider, such losses and related direct costs must be directly assigned to Medicare for reimbursement.

(Sections 1102, 1814(b), 1861(v)(1) of the Social Security Act (42 U.S.C. 1302, 1395f(b), 1395x(v), 1395hh).)

(Catalog of Federal Domestic Assistance Program No. 13.773, Medicare—Hospital Insurance; No. 13.774, Medicare—Supplementary Medical Insurance.)

Dated: May 23, 1979.

Leonard D. Schaeffer,
Administrator, Health Care Financing Administration.

Approved: May 24, 1979.

Joseph A. Califano, Jr.
Secretary.